REMARKS

The Official Action dated June 20, 2006 has been carefully considered. It is believed that the present Amendment places this application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 1 has been cancelled and claims 2-17 are added. Support for these claims may be found throughout the present specification. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, claim 1 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted that various terms within claim 1 were indefinite, confusing, vague or unclear. Although this rejection is traversed, claim 1 has been cancelled from the application and claims 2-17 are presented herein. It is believed that independent claim 2, and claims 3-17 depending therefrom, avoid the various terms and phrases objected to by the Examiner in claim 1 and define the invention in a manner that is definite to one of ordinary skill in the art in accordance with the requirements of 35 U.S.C. §112, second paragraph. It is therefore believed that the rejection has been overcome, and reconsideration is respectfully requested.

Claim 1 was rejected under 35 U.S.C. §102(e) as being anticipated by the Doshi et al U.S. Patent No. 5,766,552 and under 35 U.S.C. §102(b) as being anticipated by the Lönnberg et al WO 96/22532 and as being anticipated by the Fitzpatrick U.S. Patent No. 5,451,504. These rejections are traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 2, the present invention is directed to a test kit for determining the binding capability of ligand to an analyte. The kit comprises a flow matrix comprising an application zone for analyte, a detection zone and a separation zone. A biospecific affinity capture reactant directed toward the analyte or toward analyte-related

reactant is firmly anchored in the detection zone, and a separation zone is arranged between the application zone for analyte and the detection zone. The separation zone contains a ligand for which the binding capacity for the analyte is to be determined. Optionally, the kit may further include an analytically detectable reactant having biospecific affinity to either the analyte or the capturer reactant. As described in the present specification, for example at page 15, lines 4-11, the test kits according to the invention are particularly suitable for determining the binding capability of an analyte for the ligand contained in the separation zone. In a specific example, the test kit may be advantageous for screening of a library of compounds, with one or more of the library members arranged as ligands in the separation zone.

Doshi et al disclose an apparatus for red blood cell separation wherein whole blood is introduced to an absorbent pad impregnated with a mixture of an agglutinating agent and nucleating particles and then passes to a secondary filter for final separation of any leftover red blood cells that remain in the sample (column 15, lines 45-55). However, Applicants find no teaching by Doshi et al relating to a test kit as recited in claim 2, wherein a flow matrix comprises an application zone for an analyte, a detection zone in which a biospecific affinity capturer reactant directed toward the analyte or toward an analyte reactant is firmly anchored, and a separation zone between the application zone for analyte and the detection zone, particularly wherein the separation zone contains a ligand for which the binding capacity for the analyte is to be determined. Specifically, while the absorbent pad of Doshi et al is impregnated with a mixture of an agglutinating agent and nucleating particles, which physically separate red blood cells, Applicants find no teaching of a separation zone containing a ligand for which the binding capacity for the analyte is to be determined.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In*

re Robertson, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). In view of the deficiencies in the teachings of Doshi et al noted above, Doshi et al do not describe each and every element of claim 2, or claims 3-17 dependent thereon. Accordingly, Doshi et al do not anticipate the present claims under 35 U.S.C. §102.

Lönnberg et al disclose an immunoassay method and reagent involving suspendible carbon labelled bioaffine particles. Fig. 1 of Lönnberg et al disclose an embodiment of the test strip of the invention for determining total IgE with the aid of a sandwich test using solid-phase bound anti-IgE antibodies bound in a detection zone, labelled anti-IgE antibodies and a control zone containing solid-phase bound anti-IgG antibodies. A sample application zone is located in the lower part of the strip and the labelled anti-IgE antibodies are mixed with sample prior to its application to the strip (page 4, lines 25-33). However, Applicants find no teaching by Lönnberg et al relating to a test kit including a flow matrix as recited in claim 2, wherein a separation zone arranged between the application zone for analyte and a detection zone containing biospecific affinity capturer reagent contains a ligand for which the binding capacity for the analyte is to be determined. The Lönnberg et al disclosure employs suspendible carbon particles as a label but provides no teaching of a test kit for determining the binding capability of a ligand to an analyte as presently claimed.

In view of the failure of Lönnberg et al to teach a test kit including a flow matrix as presently claimed, Lönnberg et al do not describe each and every element of claim 2, or claims 3-17 dependent thereon. Thus, Lönnberg et al do not anticipate these claims under 35 U.S.C. §102.

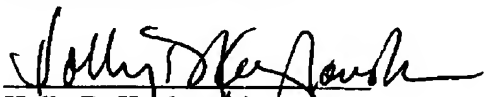
Finally, Fitzpatrick et al disclose an assay device for detecting the presence of an analyte in a sample wherein sample is applied to move through three zones, a mobilization zone, a trap zone and a detection zone. The trap is for unbound receptor which is not already bound to analyte (Abstract). Alternatively, if the first zone contains mobilizable ligand, the

trap zone contains immobilized receptor (column 6, lines 42-44). However, Applicants find no teaching by Fitzpatrick et al of a test kit including a flow matrix as recited in claim 2, including an application zone, a detection zone and a separation zone, wherein the detection zone contains biospecific affinity capturer reactant firmly anchored therein and the separation zone contains a ligand for which the binding capacity for the analyte is to be determined. In view of the failure of Fitzpatrick et al to disclose such a flow matrix, Fitzpatrick et al do not describe each and every element as set forth in claim 2, or claims 3-17 dependent thereon. Thus, Fitzpatrick et al do not anticipate these claims under 35 U.S.C. §102.

Accordingly, the test kits defined by claims 2-17 are not anticipated by and are patentably distinguishable from Doshi et al, Lönnberg et al and Fitzpatrick et al, whereby the rejections under 35 U.S.C. §102 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§102 and 112, second paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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